desired antigen. Standard coupling and cross-linking methodologies are known in the art. An alternative preparation incorporates the antigen into a lipid-particle which does not contain a nucleic acid, and these particles are mixed with lipid-nucleic acid particles prior to administration to the patient.

B.2 Characterization of compositions of the invention.

Regardless of the technique employed for their manufacture, the compositions of the invention have the following preferred characteristics.

The lipid-nucleic acid particles of the invention comprise a lipid membrane (generally a phospholipid bilayer) exterior which fully encapsulates an interior space. These particles, also sometimes herein called lipid membrane vesicles, are small particles with mean diameter 50-200 nm, preferably 60-130 nm. Most preferred for intravenous administrations are particles are of a relatively uniform size wherein 95% of particles are within 30 nm of the mean. The nucleic acid and other bioactive agents are contained in the interior space, or associated with an interior surface of the encapsulating membrane.

"Fully encapsulated" means that the nucleic acid in the particles is not significantly degraded after exposure to serum or a nuclease assay that would significantly degrade free DNA. In a fully encapsulated system, preferably less than 25% of particle nucleic acid is degraded in a treatment that would normally degrade 100% of free nucleic acid, more preferably less than 10% and most preferably less than 5% of the particle nucleic acid is degraded. Alternatively, full encapsulation may be determined by an Oligreen™ assay . Fully encapsulated also suggests that the particles are serum stable, that is, that they do not rapidly decompose into their component parts upon *in vivo* administration.

These characteristics distinguish the key particles of the invention from lipid-nucleic acid aggregates (also known as cationic complexes or lipoplexes) such as DOTMA/DOPE (LIPOFECTIN™) formulations. These aggregates are generally much larger (>250 nm) diameter, they do not competently withstand nuclease digestion, and they generally